

WHAT IS CLAIMED IS:

1. A method for sterilizing drug coated medical devices, the method comprising the steps of:

5 positioning at least one packaged, drug coated medical device in a sterilization chamber;

creating a vacuum in the sterilization chamber;

10 increasing and maintaining the temperature in the sterilization chamber in the range from about twenty-five degrees C to about thirty-five degrees C and the relative humidity in the sterilization chamber in the range from about forty percent to about eighty-five percent for a first predetermined period;

15 injecting a sterilization agent at a predetermined concentration into the sterilization chamber and maintaining the temperature in the sterilization chamber in the range from about twenty-five degrees C to about thirty-five degrees C and the relative humidity in the range from about forty percent to about eighty-five percent for a second predetermined period; and

20 removing the sterilization agent from the sterilization chamber through a plurality of vacuum and nitrogen washes over a third predetermined period, the temperature in the sterilization chamber being maintained at a temperature in the range from about thirty degrees C to about forty degrees C.

25 2. The method for sterilizing drug coated medical devices according to Claim 1, wherein the step of creating a vacuum includes reducing the pressure in the sterilization chamber to under approximately ten kPa.

3. The method for sterilizing drug coated medical devices according to Claim 2, wherein the first predetermined period of time is approximately three hours.

30 4. The method for sterilizing drug coated medical devices according to Claim 3, wherein the step of injecting a sterilization agent into the sterilization chamber comprises injecting gaseous ethylene oxide at a concentration in the range from about two-hundred mg/l to about one thousand

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two hundred mg/l and the second predetermined period of time is approximately six hours.

5. The method for sterilizing drug coated medical devices according to Claim 4, wherein the step of injecting a sterilization agent into the sterilization chamber comprises injecting gaseous ethylene oxide at a concentration in the range from about eight-hundred mg/l to about nine hundred fifty mg/l and the second predetermined period of time is approximately six hours.

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6. The method for sterilizing drug coated medical devices according to Claim 5, wherein the step of removing the sterilization agent from the sterilization chamber includes a series of alternating vacuum and nitrogen injection stages and the third predetermined period of time is in the range from about two hours to about forty-eight hours.

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7. The method for sterilizing drug coated medical devices according to Claim 1, wherein the method further comprises the step of removing the sterilization agent from the at least one packaged, drug coated medical device.

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8. The method for sterilizing drug coated medical devices according to Claim 7, wherein the step of removing the sterilization agent from the at least one packaged, drug coated medical device comprises the steps of:

removing the at least one packaged, drug coated medical device from the sterilization chamber and positioning the at least one packaged, drug coated medical device in a controlled environment;

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circulating ambient air through the controlled environment; and

maintaining the temperature in the controlled environment in the range from about ten degrees C to about seventy degrees C, the at least one packaged, drug coated medical device is maintained in the controlled environment for a length of time in the range from about one hour to about two weeks.

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9. The method for sterilizing drug coated medical devices according to Claim 8, wherein the step of removing the sterilization agent from the at least one packaged, drug coated medical device comprises the steps of:

removing the at least one packaged, drug coated medical device from the sterilization chamber and positioning the at least one packaged, drug coated medical device in a controlled environment;

circulating ambient air through the controlled environment; and

maintaining the temperature in the controlled environment in the range from about ten degrees C to about seventy degrees C, the at least one packaged, drug coated medical device is maintained in the controlled environment for a length of time in the range from about twelve hours to about seven days.

10. The method for sterilizing drug coated medical devices according to Claim 1, wherein the drug coated medical device comprises:

a biocompatible vehicle affixed to at least a portion of the medical device; and

at least one agent in therapeutic dosages incorporated into the biocompatible vehicle.

11. The method for sterilizing drug coated medical devices according to Claim 10, wherein the polymeric matrix comprises poly(ethylene-co-vinylacetate) and polybutylmethacrylate.

12. The method for sterilizing drug coated medical devices according to Claim 10, wherein the polymeric matrix comprises first and second layers, the first layer making contact with at least a portion of the medical device and comprising a solution of poly(ethylene-co-vinylacetate) and polybutylmethacrylate, and the second layer comprising polybutylmethacrylate.

13. The method for sterilizing drug coated medical devices according to Claim 12, wherein the at least one agent is incorporated into the first layer.

14. The method for sterilizing drug coated medical devices according to Claim 10, wherein the biocompatible vehicle comprises a polyfluoro copolymer comprising polymerized residue of a first moiety selected from the group consisting of vinylidene fluoride and tetrafluoroethylene, and polymerized residue of a second moiety other than the first moiety and which is copolymerized with the first moiety, thereby producing the polyfluoro copolymer, wherein the relative amounts of the polymerized residue of the first moiety and the polymerized residue of the second moiety are effective to produce the biocompatible coating with properties effective for use in coating implantable medical devices when the coated medical device is subjected to a predetermined maximum temperature, and a solvent in which the polyfluoro copolymer is substantially soluble.

15. The method for sterilizing drug coated medical devices according to Claim 14, wherein the polyfluoro copolymer comprises from about 50 to about 92 weight percent of the polymerized residue of the first moiety copolymerized with from about 50 to about 8 weight percent of the polymerized residue of the second moiety.

16. The method for sterilizing drug coated medical devices according to Claim 14, wherein said polyfluoro copolymer comprises from about 50 to about 85 weight percent of polymerized residue of vinylidene fluoride copolymerized with from about 50 to about 15 weight percent of the polymerized residue of the second moiety.

17. The method for sterilizing drug coated medical devices according to Claim 14, wherein the copolymer comprises from about 55 to about 65 weight percent of the polymerized residue of the vinylidene fluoride copolymerized with from about 45 to about 35 weight percent of the polymerized residue of the second moiety.

18. The method for sterilizing drug coated medical devices according to Claim 14, wherein the second moiety is selected from the group consisting

of hexafluoropropylene, tetrafluoroethylene, vinylidene fluoride, 1-hydropentafluoropropylene, perfluoro (methyl vinyl ether), chlorotrifluoroethylene, pentafluoropropene, trifluoroethylene, hexafluoroacetone and hexafluoroisobutylene.

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19. The method for sterilizing drug coated medical devices according to Claim 14, wherein the second moiety is hexafluoropropylene.

20. A method for sterilizing drug coated medical devices, the method comprising the steps of:

10 loading the at least one packaged, drug coated medical device in a preconditioning chamber, the preconditioning chamber being maintained at a first predetermined temperature and a first predetermined relative humidity for a first predetermined time period;

15 positioning at least one packaged, drug coated medical device in a sterilization chamber;

creating a vacuum in the sterilization chamber;

increasing and maintaining the temperature in the sterilization chamber in the range from about twenty-five degrees C to about thirty-five degrees C and the relative humidity in the sterilization chamber in the range from about
20 forty percent to about eighty-five percent for a first predetermined period;

injecting a sterilization agent at a predetermined concentration into the sterilization chamber and maintaining the temperature in the sterilization chamber in the range from about twenty-five degrees C to about thirty-five
25 degrees C and the relative humidity in the range from about forty percent to about eighty-five percent for a second predetermined period; and

removing the sterilization agent from the sterilization chamber through a plurality of vacuum and nitrogen washes over a third predetermined period, the temperature in the sterilization chamber being maintained at a temperature in
30 the range from about thirty degrees C to about forty degrees C.

21. The method for sterilizing drug coated medical devices according to Claim 20, wherein the step of loading the at least one packaged, drug

09966783-092801

coated medical device in a preconditioning chamber, includes maintaining the temperature in the range from about ten degrees C to about seventy degrees C, the relative humidity in the range from about twenty percent to about ninety-five percent for a period of time ranging from about one hour to about five days.

22. The method for sterilizing drug coated medical devices according to Claim 21, wherein the step of loading the at least one packaged, drug coated medical device in a preconditioning chamber, includes maintaining the temperature in the range from about twenty-seven degrees C to about thirty-two degrees C, the relative humidity in the range from about fifty percent to about seventy percent for a period of time ranging from about five hours to about seven hours.

23. The method for sterilizing drug coated medical devices according to Claim 22, wherein the step of creating a vacuum includes reducing the pressure in the sterilization chamber to under approximately ten kPa.

24. The method for sterilizing drug coated medical devices according to Claim 23, wherein the first predetermined period of time is approximately three hours.

25. The method for sterilizing drug coated medical devices according to Claim 24, wherein the step of injecting a sterilization agent into the sterilization chamber comprises injecting gaseous ethylene oxide at a concentration in the range from about two-hundred mg/l to about one thousand two hundred mg/l and the second predetermined period of time is approximately six hours.

26. The method for sterilizing drug coated medical devices according to Claim 25, wherein the step of injecting a sterilization agent into the sterilization chamber comprises injecting gaseous ethylene oxide at a concentration in the range from about eight-hundred mg/l to about nine-

hundred fifty mg/l and the second predetermined period of time is approximately six hours.

27. The method for sterilizing drug coated medical devices according to Claim 26, wherein the step of removing the sterilization agent from the sterilization chamber includes a series of alternating vacuum and nitrogen injection stages and the third predetermined period of time is in the range from about two hours to about forty-eight hours.

28. The method for sterilizing drug coated medical devices according to Claim 20, wherein the method further comprises the step of removing the sterilization agent from the at least one packaged, drug coated medical device.

29. The method for sterilizing drug coated medical devices according to Claim 28, wherein the step of removing the sterilization agent from the at least one packaged, drug coated medical device comprises the steps of:

removing the at least one packaged, drug coated medical device from the sterilization chamber and positioning the at least one packaged, drug coated medical device in a controlled environment;

circulating ambient air through the controlled environment; and

maintaining the temperature in the controlled environment in the range from about ten degrees C to about seventy degrees C, the at least one packaged, drug coated medical device is maintained in the controlled environment for a length of time in the range from about one hour to about two weeks.

30. The method for sterilizing drug coated medical devices according to Claim 29, wherein the step of removing the sterilization agent from the at least one packaged, drug coated medical device comprises the steps of:

removing the at least one packaged, drug coated medical device from the sterilization chamber and positioning the at least one packaged, drug coated medical device in a controlled environment;

circulating ambient air through the controlled environment; and

maintaining the temperature in the controlled environment in the range from about ten degrees C to about seventy degrees C, the at least one packaged, drug coated medical device is maintained in the controlled environment for a length of time in the range from about twelve hours to about seven days.

31. The method for sterilizing drug coated medical devices according to Claim 20, wherein the drug coated medical device comprises:

a biocompatible vehicle affixed to at least a portion of the medical device; and

at least one agent in therapeutic dosages incorporated into the biocompatible vehicle.

32. The method for sterilizing drug coated medical devices according to Claim 20, wherein the polymeric matrix comprises poly(ethylene-co-vinylacetate) and polybutylmethacrylate.

33. The method for sterilizing drug coated medical devices according to Claim 20, wherein the polymeric matrix comprises first and second layers, the first layer making contact with at least a portion of the medical device and comprising a solution of poly(ethylene-co-vinylacetate) and polybutylmethacrylate, and the second layer comprising polybutylmethacrylate.

34. The method for sterilizing drug coated medical devices according to Claim 33, wherein the at least one agent is incorporated into the first layer.

35. The method for sterilizing drug coated medical devices according to Claim 20, wherein the biocompatible vehicle comprises a polyfluoro copolymer comprising polymerized residue of a first moiety selected from the group consisting of vinylidene fluoride and tetrafluoroethylene, and polymerized residue of a second moiety other than the first moiety and which is copolymerized with the first moiety, thereby producing the polyfluoro copolymer, wherein the relative amounts of the polymerized residue of the first

moiety and the polymerized residue of the second moiety are effective to produce the biocompatible coating with properties effective for use in coating implantable medical devices when the coated medical device is subjected to a predetermined maximum temperature, and a solvent in which the polyfluoro copolymer is substantially soluble.

36. The method for sterilizing drug coated medical devices according to Claim 35, wherein the polyfluoro copolymer comprises from about 50 to about 92 weight percent of the polymerized residue of the first moiety copolymerized with from about 50 to about 8 weight percent of the polymerized residue of the second moiety.

37. The method for sterilizing drug coated medical devices according to Claim 35, wherein said polyfluoro copolymer comprises from about 50 to about 85 weight percent of polymerized residue of vinylidene fluoride copolymerized with from about 50 to about 15 weight percent of the polymerized residue of the second moiety.

38. The method for sterilizing drug coated medical devices according to Claim 35, wherein the copolymer comprises from about 55 to about 65 weight percent of the polymerized residue of the vinylidene fluoride copolymerized with from about 45 to about 35 weight percent of the polymerized residue of the second moiety.

39. The method for sterilizing drug coated medical devices according to Claim 35, wherein the second moiety is selected from the group consisting of hexafluoropropylene, tetrafluoroethylene, vinylidene fluoride, 1-hydropentafluoropropylene, perfluoro (methyl vinyl ether), chlorotrifluoroethylene, pentafluoropropene, trifluoroethylene, hexafluoroacetone and hexafluoroisobutylene.

40. The method for sterilizing drug coated medical devices according to Claim 35, wherein the second moiety is hexafluoropropylene.